Amendments to the Claims

1. (Currently amended) A method for enhancing the intracellular delivery of a nucleic acid-based drug in a mammal comprising administering to the mammal, in combination with the nucleic acid-based drug, an enhancer in an amount effective to enhance the intracellular delivery of the nucleic acid-based drug,

wherein said enhancer consists of a fatty acid or an ether, salt or anionic derivative thereof, wherein said fatty acid has a carbon chain length of from 8 to 14 carbon atoms;

said intracellular delivery is delivery into the cytoplasm and/or nucleus of a cell resulting in homogenous distribution of the nucleic acid-based compound in the cytoplasm and/or nucleus; and

said intracellular delivery is facilitated by contacting said cell with an effective concentration of said enhancer.

2. (Withdrawn) An in vitro method for enhancing the intracellular delivery of a nucleic acid-based drug in a mammalian cell or tissue sample comprising contacting the cells or tissue with the nucleic acid-based drug and contacting the cells or tissue with an enhancer in an amount effective to enhance the intracellular delivery of the nucleic acid-based drug.

3. to 31. (Canceled)

32. (Withdrawn) A pharmaceutical composition for enhancing the intracellular delivery of a nucleic acid-based drug comprising (1) a pharmaceutically effective amount of a nucleic acid-based drug and (2) an enhancer in an amount effective to enhance the intracellular delivery of the nucleic acid-based drug.

33. to 42. (Canceled)

43. (New) The method of claim 1 wherein the enhancer is caprylic acid, nonanoic acid, capric acid, or an ether, salt or an anionic derivative thereof.

44. (New) The method of claim 43 wherein the enhancer is caprylic acid, capric acid or an ether, salt or an anionic derivative thereof.

45. (New) The method of claim 44 wherein the enhancer is caprylic acid or an ether, salt or an anionic derivative thereof.

46. (New) The method of claim 1 wherein the enhancer is a sodium salt of a fatty acid.

47. (New) The method of claim 1 wherein said cell is an epithelial cell.

48. (New) The method of claim 1 wherein said cell is from the gastrointestinal tract.

49. (New) The method or use of claim 48 wherein said cell is in the small intestine.

50. (New) The method of claim 1, wherein the nucleic acid-based drug is selected from the group consisting of an oligonucleotide, an antisense oligonucleotide, a plasmid DNA, a gene, a ribozyme, a gene-correcting oligonucleotide, a triple-helix forming oligonucleotide, and an oligonucleotide which functions as an adjuvant.

51. (New) The method of claim 50, wherein said oligonucleotide is selected from the group consisting of an oligonucleotide having a modified backbone chemistry, an oligonucleotide having a modified sugar or terminal group, a chimeric oligonucleotide comprised of nucleotides of different chemistries, and an oligonucleotide having MOE chemistry.

52. (New) The method or use of claim 51, wherein the gene is selected from a gene coding for a protein, a gene coding for an RNA molecule which functions in an antisense capacity when expressed within mammalian cells and a gene coding for a ribozyme.

53. (New) The method of claim 1, wherein the amount of enhancer effective to enhance the intracellular delivery is about 0.01mM to 1M.

54. (New) The method or use of claim 53, wherein the amount of enhancer effective to enhance the intracellular delivery is about 1mM to 100mM.

55. (New) The method of claim 1, wherein the molar ratio of the enhancer to the nucleic acid-based drug is 1:100 to 100:1.

56. (New) The method of claim 1, wherein the enhancer is prepared in a form suitable for oral administration.

57. (New) The method of claim 1 wherein the nucleic acid-based drug is complexed with a cationic lipid.

58. (New) The method of claim 1 wherein the nucleic acid-based drug is complexed with a polymer system.

59. (New) The method of claim 1 wherein the nucleic acid-based drug is entrapped in a polymer system.

60. (New) The method or use of claim 58 or 59, wherein the polymer system is selected from the group consisting of a polyethyleneimine system, a polyanhydride system, a chitosan system, a cellulose system, a dendrimeric based system, and PLGA particles.

61. (New) The method of claim 1 wherein an inhibitor of an enzyme that degrades the nucleic acid-based drug or which transports a nucleic acid-based drug back out of the cell is also brought into contact with said cell.

62. (New) The method or use of claim 61 wherein the inhibitor is a P-glycoprotein inhibitor.

63. (New) The method of claim 1 wherein an endosome escape/nuclear accumulation agent is also brought into contact with said cell.

64. (New) The method of claim 1 wherein the nucleic acid-based drug is condensed by a DNA condensing agent.

65. (New) The method of claim 1 wherein condensed DNA is complexed with cationic lipid and is brought into contact with said cell simultaneously with the enhancer.